

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

Date: 12/19/2016

GAIN Report Number: VM6071

Vietnam

Agricultural Biotechnology Annual

2016

Approved By:

Mark Dries

Prepared By:

Bui Huong and Benjamin Petlock

Report Highlights:

During 2016, the Government of Vietnam (GVN) continued its policy of adopting agricultural biotechnology and has made significant progress in reviewing and approving individual biotech traits for cultivation and food and feed use. Following official commercialization in 2015, Vietnam is estimated to have grown approximately 3,500 ha of biotech corn during 2015. Vietnam also continued to make progress reviewing and approving biotech events for food and feed use and is preparing to enforce mandatory biotech labelling for certain pre-packaged food products in early 2017.

Table of Contents

REPORT HIGHLIO	GHTS	.Error! Bookmark not defined.
SECTION I: EXEC	UTIVE SUMMARY	2
SECTION II: PLAI	NT AND ANIMAL BIOTECHNOLOGY	3
CHAPTER 1:	PLANT BIOTECHNOLOGY	3
PART A:	Production and Trade	3
PART B:	Policy	6
PART C:	Marketing	
CHAPTER 2:	ANIMAL BIOTECHNOLOGY	16
PART D:	Production and Trade	
PART E:	Policy	
PART F:	Marketing	17

SECTION I: EXECUTIVE SUMMARY

Between June 2015 and October 2016, the Ministry of Agriculture and Rural Development (MARD)'s Crop Production Department (CPD) approved 17 biotech corn varieties for growing in Vietnam. These approvals follow the first three biotech corn varieties permitted for cultivation in March 2015. All of the approved biotech varieties carry a genetically engineered (GE) corn trait tolerant to either *Lepidopteran* or *glyphosate* separately or *Lepidopteran* and *glyphosate* together. According to biotech companies, the majority of the approved biotech corn varieties being commercialized in Vietnam are stacked corn events, mainly due to farmer preferences.

The deadline for dossiers registering GE events for approval for use as food and feed in Vietnam was as regulated by MARD Circular 6/2015/TT-BNNPTN. To date, MARD has received 42 GE event dossiers and has issued 18 certificates for use as food and feed events, all of which were for soybean and corn. The remaining 24 GE events for soybean, corn, cotton, canola, sugar beet, and alfalfa are still under review.

Inter-Ministerial Circular 45/2015/TTLT-BNNPTNT-BKHCN of MARD and the Ministry of Science and Technology (MOST) dated November 23, 2015 guides the labeling of pre-packaged food products containing at least five percent GE ingredients (determined by volume). The regulation has been in effect since January 8, 2016 and will be fully implemented on January 8, 2017, after which, Vietnam will prevent the sale or circulation of any pre-packaged food subject to this regulation and not labelled accordingly. This Circular does not apply to: 1) pre-packaged food products containing GE ingredients

that cannot be detected in the final product; 2) fresh, un-packaged GE food products; and 3) GE food used in emergency cases, such as natural disasters or disease epidemics.

On April 12, 2016, MARD's Plant Protection Department (PPD) issued the Official Letter 611/BVTV-QLT suspending any new registrations of plant products containing the active ingredients *Glyphosate*, *Diazinon, Malathion*, and *Tetrachlorvinphos*. The suspension is in effect from April 12 to December 31, 2016. According to unofficial sources, MARD has not yet indicated any intention to end this suspension.

Background:

By the first quarter of 2014, the GVN had published all the necessary regulations required to review and approve biotech traits for commercialization, and biotech developers began submitting application dossiers for biosafety and food/feed approval.

On September 5, 2014, MARD issued Circular 29/2014/TT-BNNPTNT regarding the exceptional recognition of biotechnological advances. As a result, the owner of a crop variety carrying an approved GE event may register for the status of "exceptional recognition" which permits new crop varieties to be grown without requiring further field testing. For a crop to be eligible for this status, its host variety for the GE trait must already have been tested for comparison with the original variety (without the GE trait) via confined and multi-location field trials, as regulated by MARD (see VM2071). This Circular streamlined the approval process, making further field testing minimal after a GE event has been evaluated for safety and approved. Please note that the approved event carrying the host variety must be on the List of crop varieties approved for cultivation in Vietnam and, if not, then the variety must first go through separate field testing for approval as a new crop variety. This requirement is regulated in MARD's Decision 95/2007/QD-BNN dated November 27, 2007 regarding the regulation on recognition of a new agricultural crop variety. Decision 95/2007/QD-BNN is available in Vietnamese on CPD's website at: http://cuctrongtrot.gov.vn/ctt/vbpl/DetailDocument.aspx?ObjectID=379

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Field Trials:

In early 2016, MARD issued a permit allowing a biotech company to conduct a confined field trial for a biotech corn variety carrying an insect resistant trait. The company expects to complete two consecutive confined field trials and one multi-location field trial by the end of 2017.

During this year, one biotech company performed a multi-location field trial for a biotech corn event carrying a single insect-resistant trait, as well with two sets of field trials taking place in Northern and Southern Vietnam. All field trials were reported harvested in mid-2016 and reports on the field trial results are being prepared at this time.

Vietnam Ministry of Natural Resources and Environment (MONRE) issues Biosafety Certificates:

Between June 2015 to November 2016, MONRE issued biosafety certificates for five GE corn events (one single event and four stacked events). The single event contains a trait resistant to *glyphosate* or *Lepidopteran* with the stacked events containing traits resistant to both *glyphosate* and *Lepidopteran*. The list of GE traits granted a Biosafety Certificate is available at MONRE's website: http://antoansinhhoc.vn/Noi-dung-don/Danh-muc-GMO/2452502

MONRE approves these events in accordance with Circular 8/2013/TT-BTNMT covering procedures for issuing and revoking bio-certificates (see GAIN VM3042) which states that biotech developers are only eligible to submit applications for Biosafety Certificates for GE events that MARD has already approved for use as food and feed.

MARD issues Certificates on the Approval of GE plants for Use as Food and Feed:

The deadline to submit dossiers for GE events for food and feed approval was March 10, 2016. According to MARD's Department of Science, Technology, and the Environment (DOSTE), the Food and Feed Committee has approved a total of 18 GE corn and soybean events for use as food and feed in Vietnam at this time. MARD also received dossiers for an additional 24 GE events requesting food/feed approval. MARD is currently reviewing GE events for corn, soybeans, cotton, canola, sugar beet, and alfalfa. The lists of approved GE events and the List of received GE dossiers are available at MARD's website: http://www.agrobiotech.gov.vn/web/default.aspx?Lang=vi-VN

b) COMMERCIAL PRODUCTION:

In practice, the biotech corn varieties commercialized in Vietnam are mainly stacked events due to the preference of farmers. Industry sources also report that approved biotech corn is growing in all regions of Vietnam where host varieties had been cultivated. Official 2015 production data for biotech corn in Vietnam is not yet available, but the International Service for the Acquisition of Agri-biotech Application's (ISAAA) 2016 Annual Report estimates Vietnam's biotech corn area in 2015 at 3,500 ha. Despite the lack of production data, farmers reported that, although the 2015 yield of biotech corn was less than expected due to extreme weather conditions, this amount was equal to or slightly higher than conventional varieties. Although MARD has been encouraging rice farmers to switch to corn, this transition remains challenged by the competitiveness of rice production due to higher paddy prices.

However, in some key corn production areas, such as Son La Province, farmers have shown interest in growing biotech corn as it is anticipated to reduce labor costs.

c) EXPORTS:

According to unofficial sources, Vietnam's MY2015/2016 exports of corn to China will continue at the same level as MY2014/2015 at around 500,000 metric tons via border trade. Although these exports to China were non-GE corn, Post notes that Vietnam replaced this displacement of corn in its domestic market with the biotech variety.

d) IMPORTS

Vietnam imports a number of GE plant products, including soybeans, soybean meal, soybean oil, corn and distillers dried grain, cotton, alfalfa, and canola. Excluding imported cotton used in the textile industry, the majority of Vietnam's GE product imports are utilized as feed for the country's growing livestock and aquaculture sectors. Vietnam is increasingly dependent on imported GE feed ingredients as domestic supplies are unable to fuel these sectors' growth. According to Post's estimates, Vietnam's CY2016 imports of corn are expected to slightly increase to 2.9 million metric tons from the 2.59 million metric tons imported in CY2015 (see VM6024).

The United States was the biggest cotton fiber supplier to Vietnam in CY 2015, exporting 432 thousand metric tons (TMT) and accounting for 42 percent of total imports. For more detail, please see VM6019.

The United States continues to be the key supplier of DDGS to Vietnam, exporting 660 TMT in CY2015, an increase of three percent over the previous year. For more information, see <u>VM6040</u>. Please note that U.S. exports of DDGS to Vietnam are currently being negatively affected by MARD's recent announcement of an import suspension on these products that will take effect on December 17, 2016 due to quarantine pest detections.

In MY 2015/16, Vietnam imported about 1.75 million metric tons of soybeans, with the majority coming from Brazil and the United States (40 and 30 percent respectively). For more details, please see VM6030.

e) FOOD AID

Vietnam is not a food aid recipient.

f) TRADE BARRIERS

As of June 2016, no trade barriers affecting GE agricultural products have been reported. However, there is potential for trade restrictions to occur depending on how Vietnam implements its feed and food biotech regulations, including inspection authorities, on grain, oilseed, and feed trade. To date, enforcement of these regulations highlights the progress made by Vietnamese regulators to access and approve commercialized events already traded on the world market.

PART B: POLICY

a) REGULATORY FRAMEWORK

*¹MARD's Circular 6/2015/TT-BNNPTN extending the implementation deadline for Circular 2/2014/TT-BNNPNT to March 10, 2016.

On February 14, 2015, MARD issued Circular 6/2015 amending Clause 2, Article 18 of Circular 2/2014 regarding the approval process for issuing and withdrawing certifications for GE plants for use as food and feed. Accordingly, the deadline for submission of food/feed approval dossiers for all biotech events was extended to March 10, 2016 from the previous deadline of March 10, 2015.

*MARD's Circular 29/2014/TT-BNNTPT to amend and supplement Article 7 of MARD's Circular 23/2010/TT-BNNPTNT regarding the Recognition of biotechnological advances in agriculture and rural development.

On September 5, 2014, MARD issued Circular 29/2014 to amend and supplement some parts of Circular 23/2010 regarding the Recognition of biotechnological advances in agriculture and rural development and applying Circular 23/2010 to biotech seed varieties. Accordingly, Circular 29/2014 amends and supplements Article 7 of Circular 23/2010 as follows:

The exceptional recognition of biotechnological advances shall be applied for a crop variety that is on the list of crop varieties allowed for production and trade in Vietnam (here referred to as the host variety) containing gene-transferred events which have been granted a Certificate of Biosafety and a Certificate for Food/Feed Use and meet the following conditions: 1) the GE crop variety has been compared with the host variety and undergone a risk assessment; and 2) the GE crop variety is similar to the host variety in key traits, except for those affected by the transgenic events.

In cases where the GE variety has undergone a risk assessment in order to compare with the host variety, the owner of the risk assessed GE variety can submit a dossier applying for exceptional recognition as regulated in Article 5 of the Circular 23/2010. If the GE variety has not yet undergone a risk assessment field trial, the owner of the GE variety shall develop and submit to MARD's Crop Production Department (CPD), a plan for field trials to compare the GE variety with the host variety in accordance with Appendix 7 of Circular 23/2010. The field trials shall be conducted on a small scale and a large scale. The small scale field trial shall be conducted during one crop season in two places. The large scale field trial shall be conducted during one one location of at least one (1) hectare. The small scale field trial can be conducted before or at the same time as the large scale field trial.

The processing time to review a dossier for exceptional recognition takes about 20-25 working days. Within 20 working days upon receipt of a valid dossier, CPD shall take the lead and coordinate with DOSTE in reviewing the dossiers and shall submit a request to MARD to establish a Review Council.

6

¹ *Indicates an update from Post's previous Annual Biotechnology Report.

Members of the Review Council will evaluate the Dossier in accordance with Article 9 of Circular 23/2010.

Within five working days of the Review Council's conclusion regarding the dossier, CPD will provide DOSTE with the following documents: 1) the Letter of Submission; 2) the Notes on Appraising Council's meeting; 3) CPD's appraising report; 4) the Dossier registered for exceptional recognition; and 5) a draft of the Decision on exceptional recognition. Within five working days of receiving documents from CPD, DOSTE shall lead and coordinate with the Legal Department to review all documents provided by CPD in order to submit a request to MARD's Minister for approval and issuance of a Decision on Exceptional Recognition.

Circular's 29/2014 is available (in Vietnamese) at: http://www.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class_id=1&mode=detail&docum ent id=175906

*MARD's Circular 23/2010/TT-BNNPTNT on the Recognition of Biotechnological Advances in agriculture and rural development. On April 7, 2010, MARD issued Circular 23/2010/TT-BNNTPN regarding the Recognition of Biotechnological Advances in Agriculture and Rural Development. The Circular regulates the procedures for the registration of recognition of biotechnological advances in the field of agriculture, forestry, and fishery that are under MARD's management.

Article 4 of the Circular regulates the criteria required for a biotechnological advance to be eligible for registration. Article 5 of the Circular regulates the order and registration procedures for the recognition of biotechnological advances developed in Vietnam or a foreign country.

The registration dossier for recognition of a biotechnological advance developed in a foreign country includes: 1) Application for recognition of a biotechnological advance developed in a foreign country (Appendix 1); 2) Report on research results and production trials of the registering organization (Appendix 2); 3) Recognition (or similar) document (issued by the original country); and 4) Results of field trials, crop variety testing; animal species; pesticides; fertilizer, soil enhancing product; animal feed, veterinary product, vaccine, products used in preservation, processing of agro-forestry, fishery products, and environment treatment of registering organization. For registration to recognize GE plants, GE animals, or GE micro-organisms, in addition to the above-mentioned documents, the registering dossier must include a copy of the biosafety certificate issued by a relevant Vietnamese agency.

Circular 23/2010 is available (in Vietnamese) at MONRE's biosafety website: http://antoansinhhoc.vn/Noi-dung/Thong-tu-so-23-2010-TT-BNNPTNT/2452598

*Vietnam Ministry of Finance's (MOF) Circular 36/2014/TT-BTC promulgating the regulation on payment fees for Bio-Safety Certificate Review. On March 24, 2014, MOF issued Circular 36/2014 regarding the Regulation on Collection, Payment, Management and Use of Fees for the Appraisal of Application Dossiers for the Bio-Certification of GE Plants. The fee for each appraisal is set at VND 70

million (around \$3,300 USD based on the November 19, 2016 exchange rate). The Circular entered into force on May 15, 2014.

As stipulated by the Circular, 20 percent of the fees collected for the appraisal of each application will go to the GVN budget, while the remaining 80 percent will be managed by the appraisal agency (MONRE) for expenses related to reviewing dossiers.

Vietnam's Over-arching Biosafety Decree (see GAIN VM 2071)

On June 21, 2010, Vietnam's Prime Minister approved the Biosafety Decree 69/2010/ND-CP, replacing Vietnam's 2005 Biosafety Regulation, its first ever such document (see VM5062). The Biosafety Decree provides the legal framework for the biosafety management of genetically engineered organisms, genetic specimens, and GE-derived products (with the exception of pharmaceutical products originating from GE). Although Decree 69 entered into force August 10, 2010, it was revised by Decree 108 in 2011 to make it compliant with the provisions of Vietnam's Food Safety Law on the management of food derived from agricultural biotechnology. Additionally, Decree 108 moved the responsibility of certification for food use from the Ministry of Health (MOH) to MARD.

Table 1: Responsibilities of Vietnam's Government Agencies in Management of Bio-Safety as described in Decree 69, and amended by Decree 108

Government Agency	Role	Responsibilities
Ministry of Natural Resources and Environment (MONRE)	Acts as lead government agency in Biosafety Management;	 To issue a Biosafety Certificate To withdraw a Biosafety Certificate To develop list of GE products granted Biosafety Certificate To develop regulation on storage, package and transportation of GE products specified in the Article 1 of the Decree. To develop and manage database on GE products
Ministry of Agriculture and Rural Development (MARD)	To regulate field trials of GE crops. To approve GE products used for animal feed and food (as a result of Decree 108)	 To issue a Permit for Field Trial of GE crops To accredit MARD's agencies for conducting field trial of GE crops To conduct Field Trials of GE crops To approve GE products used for food and animal feed; GE products that can be approved for use as food and animal feed
Ministry of Science	MOST is the key government	1. Accreditation of GE research labs

and Technology (MOST)	agency managing the research and development of GE products	 2. Management of GE projects 3. To coordinate with relevant government agencies on developing of labeling regulation
Ministry of Industry and Trade (MOIT)	Post comment: Although not officially stated, MOIT's role is to participate in the development of biosafety-regulations.	To coordinate with relevant ministries including MARD to manage use of GE products as inputs in food processing industries.

Core GVN Regulations Governing Commercialization of Agricultural Biotechnology

MONRE Biosafety Certification Regulation

On May 16, 2013, MONRE published Circular 8/2013/TT-BTNMT, outlining the procedures for granting and revoking Certificates of Biosafety. Circular 8 lays out the regulatory structure to evaluate the biosafety of agricultural traits derived from biotechnology. A biosafety certificate is required before an agricultural biotech event can be commercially cultivated in Vietnam. This Circular entered into force on July 1, 2013 (see <u>VM3042</u> for more details).

MARD approved Food/Feed Use Certification Regulation

On January 24, 2014, MARD issued Circular 2/2014/TT-BNNPTNT to promulgate the Approval Process of Issuing and Withdrawing Certification for Genetically Modified Plants for use as food and feed. The Circular provides the approval process for issuing and revoking the certificate for GE plants for use as food and feed. The Circular entered into force on March 10, 2014.

MARD formed a committee to review and evaluate the dossiers consisting of 11 experts and scientists representing different Ministries, including MONRE, MARD, MOH, MOIT, the Vietnam Academy of Sciences, the Vietnam Academy of Agricultural Sciences, and the Ho Chi Minh City's Biotechnology Center. For more details, please see <u>VM4020</u>.

Additional GVN Regulations Governing Aspects of Agricultural Biotechnology

MONRE Regulations on Providing and Exchanging Information and Databases on GE Products

On August 22, 2012, MONRE issued Circular 09/2012/TT-BTNMT on the Regulation of the Provision and Exchange of Information and Databases on GE crops. The Circular entered into force on October 8, 2012. The full Circular (in Vietnamese) can be downloaded

at: http://antoansinhhoc.vn/upload/Thong%20tu%2009.2012.TT-BTNMT.pdf

The Circular applies to government agencies, local individuals, organizations, foreign individuals, and organizations carrying out activities related to the supply or exchange of information or databases on GE crops (as defined in the regulation).

Information and databases on GE crops include: 1) bilateral or multilateral agreements on the biosafety of GE plants that Vietnam participates in or has already signed; 2) Current regulations on GE plants; 3) Results of research projects and programs on the safety of GE products kept by authorized agencies; 4) Biosafety Certificates; Food/Feed Approval Certificates, Permits for Field Trials; Validation of Field Trial results; Decisions to accredit or revoke laboratories qualified for conducting research on GE products; Decisions on which facilities are allowed to conduct GE crop field trials; Permit or Decision on Imports of GE products that are not on the list of GE products allowed for use as food /feed; 5) Reports as regulated in Appendix I, II, III, IX of Decree 69; and 6) Information on field trials of GE crops, GE crop growing areas, and the list of local/foreign consultants on biosafety - and modern biotechnology and other biotech related information or documents.

GE crop databases are grouped into: the National Genetically Modified Organism (GMO) Database (developed and managed by the Vietnam Environment Administration [VEA] of MONRE; Sectorial GE crop databases developed and managed by related ministries; Local GE crop databases developed and managed by Provincial/ People's City Committees.

MOST Regulation on Guidance to Certify Laboratories Qualified for GE Research

On October 20, 2012, MOST issued Circular 20/2012/TT-BKHCN regarding the Regulation of Procedures to Certify a Lab for Permission to Conduct GMO Research. The full Circular (in Vietnamese) can be found at: http://antoansinhhoc.vn/upload/TT20_2012_BKHCN.PDF.

MOST Regulation on Biosafety Management of GE Research and Development

On November 20, 2012, MOST issued Circular 21/2012/TT-BKHCN regulating the Research and Development of Genetically Engineered Organisms in Vietnam. The Circular applies to individuals and organizations conducting research and development of GE crops and genetic specimen activities within Vietnam.

Article 4, Chapter I of Circular 21 regulates the principles of biosafety management for research on GE crops, stating that that all GE research must be in compliance with Item 19, Article 20 of the Science and Technology Law (http://antoansinhhoc.vn/Noi-dung/Luat-Khoa-hoc-va-Cong-nghe-sua-doi-2013/2452962); Article 87 of the Environment Protection Law; Article 7 of Bio-Diversity Law (Luât số-20/2008/QH12 - hongchuyen.com | 2452579); and Article 44 and 50 of the Vietnam Food Safety Law http://vanban.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?class_id=1&_page=3&mode=detail&document_id=96032

Research on GE crops must be implemented within the framework of science and technology development (project or research topics) approved by the relevant competent authorities. All research on GE products must be carried out in MOST-certified laboratories, in accordance with Circular 20/2012/TT-BKHCN.

Please contact FAS-Vietnam if you need further information regarding this Circular which can be found (in Vietnamese) at: http://antoansinhhoc.vn/upload/TT21_2012_BKHCN.PDF

b) APPROVALS

According to industry sources, MARD approved a total of 16 biotech corn varieties to be grown in Vietnam at this time. The approved biotech corn varieties carry a trait tolerant to Lepidopteran or glyphosate separately or both Lepidopteran and glyphosate together.

Vietnam Ministry of Natural Resources and Environment (MONRE) issues Biosafety Certificates:

Between June 2015 and November 2016, MONRE issued biosafety certificates for five GE corn events (one single event and four stacked events). The single event contains a trait resistant to *Glyphosate* or *Lepidopteran* with the stacked events containing traits resistant to both *Glyphosate* and *Lepidopteran*. The list of GE traits granted a Biosafety Certificate is available at MONRE's website: http://antoansinhhoc.vn/Noi-dung-don/Danh-muc-GMO/2452502.

MONRE approves these events in accordance with Circular 8/2013/TT-BTNMT covering procedures for issuing and revoking bio-certificates (see GAIN VM3042) which states that biotech developers are only eligible to submit applications for Biosafety Certificates for GE events that are already approved by MARD for use as food and feed.

MARD issues Certificates on the Approval of GE plants for Use as Food and Feed:

The deadline to submit dossiers for GE events for food and feed approval was March 10, 2016. According to MARD's Department of Science, Technology, and the Environment (DOSTE), the Food and Feed Committee has approved a total of 18 GE corn and soybean events for use as food and feed in Vietnam at this time. MARD also received dossiers for an additional 24 GE events requesting food/feed approval. MARD is currently reviewing GE events for corn, soybeans, cotton, canola, sugar beet, and alfalfa. The lists of approved GE events and the List of received GE dossiers are available at MARD's website: http://www.agrobiotech.gov.vn/web/default.aspx?Lang=vi-VN

c) STACKED or PYRAMIDED EVENT APPROVALS

According to MONRE's Circular 8/2013/TT-BTNMT dated May 16, 2013, similar to single event varieties, a stacked event variety derived from biotechnology is permitted to be considered for a Biosafety Certificate. The procedure of issuing a Biosafety Certificate is described in detail at VM3042.

Similarly, MARD Circular 2/TT-BNNPTNT, dated January 24, 2014 (see <u>VM4020</u>), regulates procedures on the issuance of the certification of approval of GE plants allowed for use as food and feed

for both single and stacked events derived from biotechnology. In both instances, MARD and MONRE will review each individual trait in a stack variety and will approve it if each of the individual traits is approved in Vietnam.

d) FIELD TESTING

On October 27, 2009, MARD issued Circular 69/2009/TT-BNNPTNT outlining the regulatory process for conducting agricultural biotech field trials before commercialization. The Circular covers both confined and multi-location field trials. Circular 69 established the criteria to evaluate entities and facilities that wish to conduct biotech field trials. Based on these requirements, MARD has approved the following institutes/agencies to conduct agricultural biotech field trials:

- The Agricultural Genetics Institute (AGI) and the Plant Protection Institute (PPI), both of which are part of the MARD Vietnam Academy for Agriculture Science (VAAS)
- The Northern and Southern New Seed Testing Centers, Crop Production Department, MARD
- The Nha Ho Cotton Research Institute

MARD also regulates which GE crops are allowed for field trials, and ultimately, commercialization, through Circular 72/2009/TT-BNNPTNT dated November 17, 2009. Thus far, only three GE crops namely: Corn (*Zea mays L.*), Cotton (*Gossypium spp.*), and Soybean [(*Glycline max (L.*) Merrill] are approved for field testing.

Although, Vietnamese regulations allow for field trials for the three aforementioned crops at this time, biotech developers and MARD have only conducted field trials for corn varieties.

e) INNOVATIVE BIOTECHNOLOGIES

Innovative biotechnology, such as genome editing technology, is new to Vietnam. Although innovative technology does not yet have a regulatory status, Vietnamese agricultural research scientists are interested in this technology. According to an unofficial source, some research using genome editing technology on agricultural crops such as rice and cassava is currently being conducted in Vietnamese laboratories.

f) COEXISTANCE

Although there is a market for certified organic products in Vietnam, it is limited due to its high price points and, as a result, there is no market for identity preserved food products. Post is currently unaware of any government regulation for organic products in Vietnam and will continue to follow the situation should MARD develop any regulations.

g) LABELING

On November 23, 2015, MARD and MOST issued the Inter-Ministerial Circular 45/2015/TTLB-BNNPTNT-BKHCN detailing guidance for the labeling of pre-packed GE foods. Inter-Ministerial

Circular 45 is applied to pre-packaged foods containing at least one GE ingredient having a content of five percent or higher of the total ingredients forming the product. In cases where Inter-Ministerial Circular 45 is applicable, the Vietnamese phrase "biến đổi gien" (aka: "genetically modified") must be printed next to the GE ingredient, on the Vietnamese secondary label affixed on the product. Circular 45 does not apply in the following cases: 1) pre-packed food which contains GE ingredients that cannot be detected in the final product; 2) fresh, raw, or unpackaged GE food; and 3) GE food products used in emergency cases such as natural disasters or disease epidemics. The Circular entered into force on January 8, 2016 and is fully effective on January 8, 2017. Please see VM 5088 for the full version of Circular 45.

h) MONITORING AND TESTING

As of November 2016, Vietnam does not have a monitoring or testing regime in place to evaluate the biotech content in imported or exported food products or food products domestically-produced for consumption in Vietnam.

i) LOW LEVEL PRESENCE (LLP) POLICY

Although, as of November 2016, Vietnam does not have a LLP policy, it is a frequent observer to the Global Low Level Presence Initiative meetings.

j) ADDITIONAL REQULATORY REQUIREMENTS

None at this time

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Under the Intellectual Property Law (IPL) 50/2005/QH11, Vietnam has a regulatory structure in place to protect the rights of plant variety developers. The IPL provides the foundation for intellectual property rights protection in Vietnam and covers plant varieties, including agricultural biotechnology. The IPL was ratified by the National Assembly (NA) in 2005 and entered into force on July 1, 2006.

Part Four (of Six) of the Law outlines the rights and protections for plant varieties as well as detailing the process for obtaining Plant Variety protection. Part Four consists of the four following chapters:

- Chapter XII: Conditions for Protection of Plant Varieties
- Chapter XIII: Establishing the Rights for Plant Varieties
- Chapter XIV: Contents and Limitations of Rights for Plant Varieties
- Chapter XV: Transfer of the Rights to a Plant Variety
- Chapter XIII (Section 2) which provides details on the application forms and process to obtain plant variety protection in Vietnam.

As stated in the Article 174, the application must include: a) a registration form using the prescribed document; b) photo and technical questionnaires using the prescribed form; c) letter of authorization if the application form is to be completed by a representative; d) documents demonstrating the right to register the variety, if the registrant has been transferred; e) documents justifying the claim for prioritization; and f) fee receipt.

Article 176 of the Law outlines the application review process, stipulating that after 15 days from the date of receiving the document, a state competent authority will examine the application to see if it qualifies for further processing, requires additional information, or should be rejected.

Article 178 outlines the content examination criteria and includes: a) examination for originality and the denomination; and b) examination of the Technical Test results of the variety. The Technical Test is conducted to determine the Distinctness, Uniformity, and Stability (DUS) of the registered variety. A competent agency or institute assigned by MARD will perform this examination.

As stated in Article 169, the Certificate of Plant Variety Protection is valid for 25 years for trees and grapes; and 20 years for other crops. The Certificate applies for the whole of Vietnam.

The full Law in English can be found at:

http://pvpo.mard.gov.vn/DetailInfomation.aspx?InfomationID=IN0000

Government Decree 88/2010/ND-CP: Decree 88 was published on August 16, 2010 and provides additional clarification on aspects of the IPL as it relates to plant variety protection. The full Decree 88 in English is available at: http://pvpo.mard.gov.vn/ImageNews/201308090928Decree_No._88-2010-ND-CP.pdf

The registration fee for the Certificate for Plant Variety Protection is stipulated in the Ministry of Finance's (MOF) Circular 92/2002/TT-BTC, dated October 12, 2002. The full Circular in English is available at: http://pvpo.mard.gov.vn/FileUpload/circular92.pdf.

To implement the IPL and Decree 88, MARD has also issued a number of Circulars. Circular 56/2007/QĐ-BNN, dated June 12, 2007; Decision 103/2007/QD-BNN, dated December 25, 2007; Circular 33 /2009/TT-BNNPTNT, dated June 10, 2009; and Circular 11/2013/TT-BNNPTNT, dated February 6, 2013, all of which provide the list of plant species protected and designate MARD agencies approved to conduct DUS testing. These decisions and circulars are available at: http://pvpo.mard.gov.vn

On February 28, 2013, MARD issued Circular 16/2013/TT-BNNPTNT which stipulates the Guidelines on the Protection of Plant Variety Rights. The Circular guides the implementation of a number of established content rights for plant varieties, representing rights to plant varieties, assessment of plant variety rights, and forms of protection of plant varieties.

1) CARTAGENA PROTOCOL RATIFICATION

The Vietnamese Government is currently developing a Decree to implement the Nagoya Protocol. A drafting team, led by MONRE, is (at the time of this report) in the process of planning and drafting the Decree which is expected to be available at the end of 2016.

On March 17, 2014, the Vietnamese Prime Minister signed Resolution 17/NQ-CP regarding Vietnam joining the Nagoya Protocol, which covers access to genetic resources, equitable sharing, and reasonable interests arising from the use of genetic resources within the Biodiversity Convention.

At this time, Vietnam has not yet disclosed details on how it will implement the Protocol. Sources report that instead of developing a separate Decree to implement the Nagoya Protocol, Vietnam may consider amending the Biosafety Decree 69/2010/ND-CP (VM2071), adding a section on Liability and Redress as recommended by a number of international consultants.

Vietnam became a member of the Cartagena Protocol in April 2004 and regularly participates in Cartagena Protocol Meetings. As stipulated by the Cartagena Protocol, the Vietnam Environment Administration (VEA) of MONRE is the Cartagena Protocol Focal Point of Vietnam. MONRE has already developed a website: www.antoansinhoc.vn which serves as the clearinghouse for biotech information, regulations, and Certificates issued by MONRE and MARD. Although Vietnam is in the beginning stage of implementing the Cartagena Protocol, its government actively tries to incorporate requirements and obligations of the Protocol into its regulations on biosafety management.

m) INTERNATIONAL TREATIES/FORA

Vietnam became a member of Codex Alimentarius in 1989 and a member of International Plant Protection Convention in 2005. The Vietnam Codex Office is under management of MOH's Vietnam Food Administration: http://codexvn.org.

n) RELATED ISSUES

None at this time

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS; b) MARKET ACCEPTANCE/STUDIES

During June 2015 to November 2016, some anti-biotech campaigns focused on disseminating negative information about GE crops, mainly via social media. Anti-biotech groups are also allied with other interest groups, such as the organic food supporters, to discourage consumers from using biotech products. Despite these developments, public opinion remains largely indifferent to the commercialization and regulatory acceptance of biotech products in the market.

Meanwhile, MARD has in general publicly expressed support for the cultivation of GE crops in Vietnam, particularly under the former Minister. The livestock, fishery, and textile/garment industries depend heavily on imported materials including soybeans, soybean meal, corn, and cotton, a the

majority of which is derived from agricultural biotechnology, and the GVN, led by MARD, clearly understands that necessity.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

As of June 2016, GVN and MARD do not have legal regulations in place governing the research and development or regulatory approval process for animal biotechnology applications. However, there is some research on gene technology for improving animal productivity, animal disease treatment, and the production of vaccine for animals utilizing biotechnology.

b) COMMERCIAL PRODUCTION

As there are no regulations in place to govern animal biotechnology, there is no commercial production in Vietnam.

c) EXPORT

None

d) IMPORT

None

e) TRADE BARRIERS

None

PART E: POLICY

a) REGULATORY FRAMEWORK

No regulations cover animal biotechnology.

b) INNOVATIVE BIOTECHNOLOGY

None

c) LABELING AND TRACEABILITY

None

d) INTERLLECTUAL PROPERTY RIGHTS

None

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

None at this time

b) MARKET ACCEPTANCE/STUDIES

None